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U.S. ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND
Aberdeen Proving Ground, MD 21010-5424

ECBC-TR-1392

RECOMMENDATIONS ON THE USE OF DIAGNOSTIC DEVICES IN FAR-FORWARD MILITARY OPERATIONS

Peter A. Emanuel

RESEARCH AND TECHNOLOGY DIRECTORATE

Lorenzo W. Hankla

BOOZ ALLEN HAMILTON
Belcamp, MD 21017-1554

October 2016

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EXECUTIVE SUMMARY

This report provides recommendations to improve the implementation and effectiveness of diagnostic capabilities used in far-forward military settings. Of specific focus are the operational concepts of operations (CONOPS), military needs, and challenges associated with implementing chemical, biological, radiological, and nuclear (CBRN) diagnostics at Roles 1 and 2 medical echelons of care, as defined in Joint Publication (JP) 4-02, *Health Service Support*, July 2012.

The findings and recommendations discussed in this report are based on the outcomes of the Far-Forward CBRN Diagnostics Concepts Development Workshop held on 17 June 2014 in Crystal City, VA. This workshop was led by leadership from the Joint U.S. Forces Korea Portal and Integrated Threat Recognition (JUPITR) Advanced Technology Demonstration (ATD), and it included over 30 specially selected participants from more than 15 organizations across the Department of Defense (DoD).

A consistent theme that emerged during the workshop was that even if technology that could provide detailed patient care information in far-forward military theaters were available, the DoD is not structured or resourced to act upon this diagnostic information. In the relatively low medically resourced environments found in Roles 1 and 2 settings, the military lacks the appropriately trained personnel, therapeutics, and related treatment options that would enable the DoD to provide early intervention treatments, regardless of their access to CBRN diagnostic information.

The rapid pace of technology development makes advancement in handheld diagnostics inevitable, and DoD members must begin positioning themselves to develop the appropriate CONOPS to deal with the incoming wave of technology. The following recommendations apply to the future implementation of handheld diagnostic capabilities in far-forward military environments:

- **Recommendation 1:** Armed services leaders should begin positioning themselves to develop the appropriate CONOPS to deal with the incoming wave of handheld diagnostics technologies, specifically when it comes to the use of diagnostics in far-forward military settings (e.g., in Roles 1 and 2 medical echelons of care, as per JP 4-02).
- **Recommendation 2:** The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) and the Joint Requirements Office for CBRN Defense (JRO-CBRND) members should consider aligning resources and prioritizing efforts to develop far-forward diagnostic capabilities that support the following three basic diagnostics-related decisions:

- medical treatment decisions (e.g., identification of bacterial versus viral targets to support treatment with antibiotics or antivirals);
 - quarantine decisions (e.g., identification of a subset of highly contagious pathogens that directly impact quarantine decisions); and
 - patient movement decisions (e.g., identification of pathogens or illnesses that require immediate patient evacuation, regardless of the patient's far-forward force protection posture).
- **Recommendation 3:** The JPEO-CBD should consider lateral flow immunoassays (LFIs) as a potential interim solution to provide Role 3 and potentially Roles 1 and 2 medical echelons of care with an easy-to-use and relatively inexpensive antibody-based diagnostic capability to identify the Next Generation Diagnostic System (NGDS) Increment (Inc) 1 objective biological targets. The workshop participants recommended that the JPEO-CBD collaborate with the U.S. Army Medical Research and Materiel Command (MRMC) for any LFI development efforts to leverage the upcoming MRMC-led LFI development and production contract.
 - **Recommendation 4:** To provide the greatest benefit for near-term CBRN diagnostics acquisition programs that may provide a far-forward diagnostic capability (i.e., NGDS Inc 2), the JRO-CBRND should increase focus on providing biological diagnostic capabilities that support the identification of biological targets not readily amenable to polymerase chain reaction analysis.

PREFACE

The work described in this report was authorized under contract number W911SR-10-D-0004. The work was started and completed in June 2016.

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CONTENTS

1.	INTRODUCTION AND BACKGROUND	1
2.	WORKSHOP OBSERVATIONS AND LESSONS LEARNED	2
3.	WORKSHOP RECOMMENDATIONS	5
	ACRONYMS AND ABBREVIATIONS	9
	APPENDIX: WORKSHOP SUMMARY	11

FIGURE

Medical roles or levels of care, as defined in JP 4-02	1
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RECOMMENDATIONS ON THE USE OF DIAGNOSTIC DEVICES IN FAR-FORWARD MILITARY OPERATIONS

1. INTRODUCTION AND BACKGROUND

Joint Publication (JP) 4-02* provides a doctrine for the planning, preparation, and support of the execution of health services across the range of military operations in which the Department of Defense (DoD) operates. DoD members achieve continuity of care and treatment by moving patients through progressive and phased roles. As seen in the Figure, these roles or levels of care extend from the place of injury or wounding to a supporting installation or support base. Each type of medical unit contributes a measured, logical increment of care appropriate to its location and capabilities.

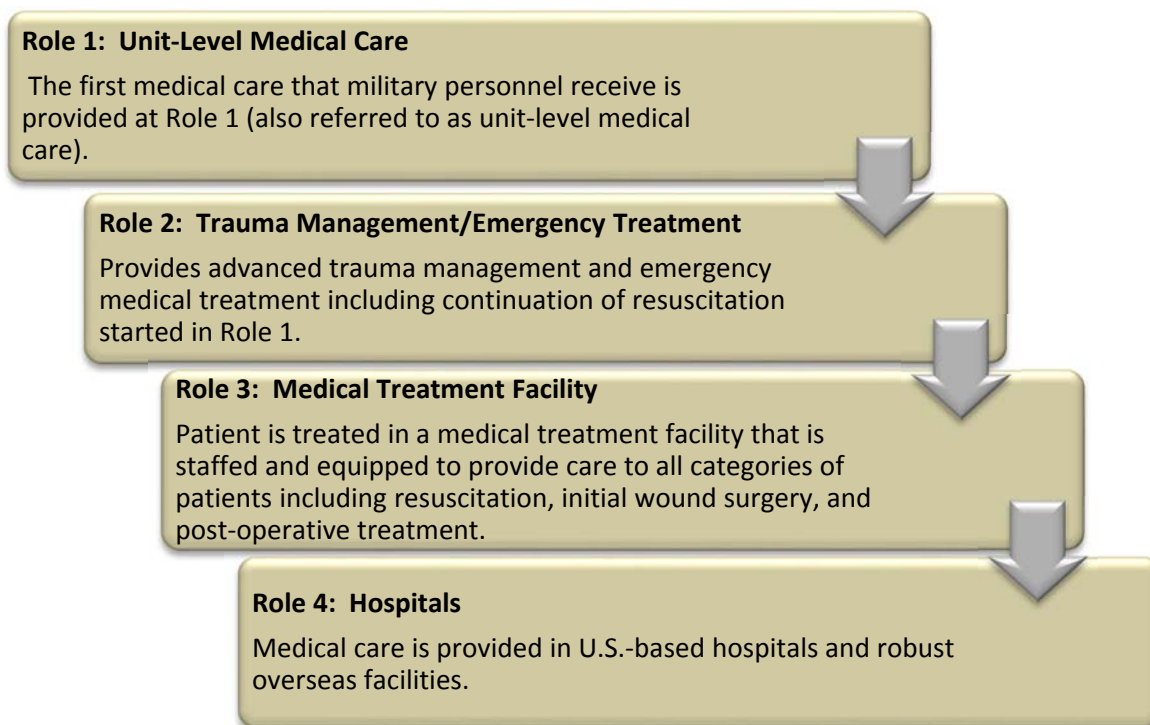


Figure. Medical roles or levels of care, as defined in JP 4-02.

Control is required to ensure that scarce medical resources are efficiently and appropriately used at each role or level and that tactical, strategic plans are supported. Control also ensures that the scope and quality of medical treatment meet professional standards, policies, and U.S. and international law. Each Service is designated to provide scalable and tailorable medical commands and control modules for early entry and expeditionary operations,

* Directorate for Joint Force Development (J7). *Health Service Support*; Joint Publication 4-02; Directorate for Joint Force Development (J7): Washington, DC, 26 July 2012; UNCLASSIFIED.

which could augment theater capabilities until an operational health care infrastructure is established.

During the Far-Forward CBRN¹ Diagnostics Concepts Development Workshop (held 17 June 2014 in Crystal City, VA), participants explored concept of operations (CONOPS) for the potential use of diagnostic devices in Role 1 or 2 settings (i.e., “far-forward” settings). Major discussion points during the workshop included the following questions:

- How far away from military medical centers does it become advantageous for the DoD to provide far-forward military diagnostics?
- What barriers exist with the use of far-forward diagnostics (i.e., clinical laboratory improvement amendments [CLIA] waiver, cold chain, etc.)?
- At what distance away from an existing medical facility should the military services focus resources for the development of additional systems or infrastructure?

The workshop included over 30 specially selected participants from more than 15 organizations across the DoD. It was facilitated by the following participants:

- Peter Emanuel, who represented the Joint U.S. Forces Korea Portal and Integrated Threat Recognition (JUPITR) Advanced Technology Demonstration (ATD);
- LTC Mark Bohannon from the Joint Requirements Office for CBRN Defense (JRO-CBRND), J8, Joint Chiefs of Staff;² and
- CDR Franca Jones from the Office of the Assistant Secretary of Defense (OASD) for Nuclear, Chemical, and Biological Defense Programs (Chemical and Biological Defense).

2. WORKSHOP OBSERVATIONS AND LESSONS LEARNED

As discussed in JP 4-02, the relatively lower casualty rates, availability of rotary-wing air ambulances, and other situational variables associated with current military theaters often enable patients to be evacuated from the place of injury (i.e., at or near Role 1) directly to the supporting medical treatment facility (i.e., Roles 3 and above). The workshop participants highlighted the likelihood that more traditional combat operations could generate higher casualty rates and extended distances from medical treatment facilities, which would necessitate that a patient receive treatment and medical diagnostics at each level of care to maintain physiologic status and enhance chances of survival.

¹ CBRN: chemical, biological, radiological, and nuclear.

² J8, Joint Chiefs of Staff: Force Structure, Resources, and Assessment Directorate (Joint Chiefs of Staff).

For Roles 1 and 2 settings, the workshop participants voiced concern that the skill set of far-forward medical personnel could result in an increase of false-positive results and unnecessary diagnostic tests. False positives and increased testing have the potential to overburden medical treatment facilities and significantly increase costs associated with the military medical enterprise. Conversely, the participants recognized the upside of far-forward diagnostics in that medical personnel have the ability to diagnose patients early. One participant noted that the oldest diagnostics capability is time, which is not considered the best technology.

- **Lesson Learned 1:** Current military theaters have evolved away from the tiered medical structure defined in JP 4-02. Future theaters will likely revert to a tiered structure and, once this occurs, a key refinement of patient care would be an efficient and cost-effective differential diagnosis at the earliest possible moment. This argues that diagnostic capabilities should be as far-forward as realistically possible.

The distribution of actionable medical diagnostic information was also discussed during the workshop. Representatives from all of the services noted that the vast majority of CONOPS do not discuss the implementation of far-forward diagnostics, especially those technologies that could be employed in Role 1 settings. One senior medical officer from the U.S. Air Force mentioned that far-forward diagnostics is only good if we can figure out what to do with the diagnostic information, how it will be transmitted, and who will do it.

Although not currently covered in most service CONOPS, all participants acknowledged that technology will progress at a rapid pace and will eventually enable small, simple, and relatively inexpensive diagnostics devices to become widely available, likely within the next decade. These technologies could be perfectly suited for use in Roles 1 and 2 settings if the service CONOPS that govern their use is further developed or refined.

- **Lesson Learned 2:** Not only should far-forward diagnostics be simple to operate, supply, and maintain, but the DoD should ensure concise CONOPS exist to help the DoD understand what to do with the diagnostic information, how it will be transmitted, and who will act on it.

During the workshop, one participant pointed out that transport of infected or sick people is not always an option. One senior medical commander noted that the U.S. Transportation Command, for example, sometimes will not transport infected individuals from theaters overseas. This highlighted one potential use of diagnostics in far-forward settings, which is the ability to distinguish between viral infections and bacterial infections, contagious and non-contagious pathogens, and specific types of illnesses (e.g., Gram positive or Gram negative). Such diagnostics information could then support decisions such as patient movement, medical treatment, and quarantine.

The workshop participants noted that the type of medical diagnostics capability used in Role 1 or 2 settings would be useful from the perspective of medical intervention at a far-forward role and would be consistent with existing staffing and expertise.

- **Lesson Learned 3:** To most-effectively influence the population management and patient-centric decision-making process, the workshop attendees discussed the potential CONOPS related to a Roles 1 and 2 triage tool that could distinguish between viral and bacterial infections, contagious and non-contagious pathogens, and specific types of illnesses (e.g., Gram positive or Gram negative).

In addition to potential CONOPS for the use of far-forward diagnostics, the participants discussed possible technologies that could improve patient care in Roles 1, 2, and 3 settings. Because the DoD has already invested in nucleic acid-based diagnostics technology (e.g., polymerase chain reaction [PCR]) through the Next Generation Diagnostic System (NGDS) Increment (Inc) 1 program, the participants discussed the potential benefit of investing in antibody-based (e.g., immunoassay) technologies.

One potential antibody-based technology that was well-received by the group was lateral flow immunoassay (LFI). LFIs are extremely simple to use, have historically received CLIA waivers, and have the potential to address a wide range of bacteria, virus, and toxin targets, especially targets listed as objectives within the NGDS Inc 1 program. If developed with a focus on stability for extended periods of time at room temperatures (or warmer), LFIs could be used in Roles 1 and 2 settings and provide diagnostic utility in Role 3 medical treatment facilities.

- **Lesson Learned 4:** The workshop participants discussed the possibility of including LFIs in Roles 1, 2, and 3 medical echelons of care as a potential interim solution until similar easy-to-use and relatively inexpensive antibody-based diagnostic technologies mature.

The workshop participants also discussed current and future DoD priorities for CBRN diagnostics in far-forward settings. The attendees specifically highlighted the need for diagnostic capabilities to identify personnel exposure to toxic industrial chemicals (TICs), chemical warfare agents (CWAs), and other chemical targets in Roles 1 and 2 settings. However, the participants acknowledged that currently available technologies that are used to diagnose exposure to the threats in far-forward settings are relatively immature. This lack of mature technologies was viewed as the reason why the use of TIC diagnostics, in particular, was infrequent over the previous 10+ years of war. The attendees drew similar conclusions for the infrequent use of radiological and nuclear diagnostics.

- **Lesson Learned 5:** During the workshop, senior-level medical commanders acknowledged the need to identify personnel exposure to TICs, CWAs, and emerging chemical threats in far-forward settings, but they recognized that the technologies needed to support such diagnostics are currently relatively immature.

3. **WORKSHOP RECOMMENDATIONS**

Because future combat scenarios will likely revert to the tiered military medical structure described in JP 4-02, medical capabilities could necessitate that a patient receive treatment and medical diagnostics at each echelon of care to maintain physiologic status and enhance chances of survival. A persistent concern that emerged during the workshop was that even if the technology that could provide detailed patient-care information in far-forward military theaters were available, the DoD was not structured or resourced to act upon this diagnostic information. In the relatively low medically resourced environments found in Roles 1 and 2 settings, the military lacks appropriately trained personnel, therapeutics, and related treatment options that would allow DoD members to provide early intervention treatments, regardless of their access to CBRN diagnostic information. Four recommendations were made:

- **Recommendation 1:** The U.S. armed services should begin positioning themselves to develop the appropriate CONOPS to deal with the incoming wave of handheld diagnostics technologies, specifically when it comes to the use of diagnostics in far-forward military settings such as in Roles 1 and 2 medical echelons of care, as per JP 4-02 (Lessons Learned 1 and 2).

During the workshop, the participants discussed the potential uses of diagnostic triage tools that could be useful from the perspective of medical intervention at a far-forward role and would be consistent with existing staffing and expertise. One senior-level participant with the OASD summarized this potential device by stating,

There would be real value in a tool that could distinguish between a bacterial infection and a viral infection to help us implement appropriate treatment options and reduce the overuse of antibiotics. It would then be advantageous to identify contagious versus non-contagious threats so I could decide if I have to quarantine the patient or possibly the entire squad. After that I'd like to begin to classify the illness into broad bins (e.g., Gram positive or Gram negative) to help us prioritize which diseases or illnesses require immediate evacuation, regardless of the patient's force protection posture.

During the workshop, several senior research scientists and medical commanders recognized that it is possible to exploit host response markers to provide answers to some of the fundamental questions required by a similar triage tool (e.g., bacteria versus viral, Gram positive

versus Gram negative, etc.). However, all of the participants recognized that concerted and focused investment would be required to develop this triage diagnostic capability.

- **Recommendation 2:** The JPEO-CBD and the JRO-CBRND should consider aligning resources and prioritizing efforts to develop far-forward diagnostic capabilities that support three basic diagnostics-related decisions (Lesson Learned 3):
 - medical treatment decisions (e.g., identification of bacterial versus viral targets to support treatment with antibiotics or antivirals);
 - quarantine decisions (e.g., identification of a subset of highly contagious pathogens that directly impact quarantine decisions); and
 - patient movement decisions (e.g., identification of pathogens or illnesses that require immediate patient evacuation, regardless of the patient's far-forward force protection posture).

Because LFIs are extremely simple to use, have historically received a CLIA waiver, and have the potential to address a wide range of bacterial, viral, and toxic targets (especially targets listed as objectives within the NGDS Inc 1 program), their use in Roles 1, 2, and 3 settings would be desirable. During the workshop, the participants noted that the U.S. Army Medical Research and Materiel Command (MRMC) is in the process of releasing a contract that would provide support to develop and produce various types of LFIs that could be used to identify toxins and pathogens of operational concern. The workshop attendees recommended that the JPEO-CBD collaborate with the MRMC to leverage this development and production contract for any LFI-related efforts.

If an LFI is developed with the ability to remain stable for extended periods of time at room temperatures (or warmer), it could be used in Roles 1 and 2 settings, as well as in Role 3 medical treatment facilities. This would provide an interim diagnostic capability until genetic sequencing technologies, combined PCR and immunoassay devices, or some other form of next generation diagnostic device is matured to the point that a capability is easily operated, maintained, and supplied by the armed services.

- **Recommendation 3:** The JPEO-CBD should consider LFIs as a potential interim solution to provide Role 3 and potentially Roles 1 and 2 medical echelons of care with an easy-to-use and relatively inexpensive antibody-based diagnostic capability to identify NGDS Inc 1 objective biological targets. The workshop participants recommended that the JPEO-CBD collaborate with MRMC personnel for LFI development efforts to leverage the upcoming MRMC-led LFI development and production contract (Lesson Learned 4).

The workshop participants also noted that although diagnostics for TICs, CWAs, emerging chemicals, and radiological and nuclear threats are currently high priorities for the DoD, mature technologies and supporting service CONOPS currently do not exist to effectively implement clinical diagnostics for these targets, especially in Roles 1 and 2 settings. It was therefore recommended that increasing biological diagnostic capabilities to support the identification of biological targets not readily amenable to PCR analysis may provide the best payoff for near-term CBRN diagnostics acquisition programs that may provide a far-forward diagnostic capability, such as the NGDS Inc 2 program.

The attendees acknowledged that existing and upcoming DoD programs established to support a Joint Health Risk Management Initial Capabilities Document and other health surveillance efforts will support the development of diagnostic and health-monitoring materiel for personnel exposure to TICs. These devices could potentially be used in far-forward settings.

- **Recommendation 4:** To provide the greatest benefit for near-term CBRN diagnostics acquisition programs that may provide a far-forward diagnostic capability (i.e., NGDS Inc 2), the JRO-CBRND should increase focus on providing biological diagnostic capabilities that support the identification of biological targets not readily amenable to PCR analysis (Lesson Learned 5).

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ACRONYMS AND ABBREVIATIONS

ATD	Advanced Technology Demonstration
CBRN	chemical, biological, radiological, and nuclear
CLIA	clinical laboratory improvement amendment
CONOPS	concept of operations
CWA	chemical warfare agent
DoD	Department of Defense
Inc	increment
J8	Force Structure, Resources, and Assessment Directorate (Joint Chiefs of Staff)
JP	Joint Publication
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
JRO-CBRND	Joint Requirements Office for CBRN Defense
JUPITR	Joint U.S. Forces Korea Portal and Integrated Threat Recognition
LFI	lateral flow immunoassay
MRMC	U.S. Army Medical Research and Materiel Command
NGDS	Next Generation Diagnostic System
OASD	Office of the Assistant Secretary of Defense
PCR	polymerase chain reaction
TIC	toxic industrial chemical

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APPENDIX WORKSHOP SUMMARY

The Far-Forward CBRN (chemical, biological, radiological, and nuclear) Diagnostics Concepts Development Workshop was held on 17 June 2014 at the Battelle corporate office in Crystal City, VA. This workshop was held because the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) Joint U.S. Forces Korea Portal and Integrated Threat Recognition (JUPITR) Advanced Technology Demonstration (ATD) has partnered with acquisition programs across the chemical and biological (CB) defense community to explore opportunities that could inform new or ongoing programs of record. The one-day, JUPITR-led workshop explored concepts of operation (CONOPS) for CBRN diagnostic capabilities that support far-forward military medical operations. These capabilities are under consideration for multiple programs across the CB Defense Program.

The workshop participants identified operational needs and challenges associated with implementing diagnostic capabilities at far-forward medical echelons of care. Working as a group, the participants proposed suggestions that, if implemented, could overcome identified challenges and potentially impact joint doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy considerations.

The workshop was facilitated by Peter Emanuel from the JUPITR ATD; LTC Mark Bohannon from the JRO-CBRND, J8, Joint Chiefs of Staff; and CDR Franca Jones from the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (Chemical and Biological Defense). Over 30 specially selected participants from more than 15 organizations across the Department of Defense (DoD) participated in the workshop.

Before the start of the workshop, the participants were asked to complete a short survey related to the potential use of diagnostic devices in a far-forward setting. This survey, developed by JUPITR ATD personnel, sought user feedback on the potential features and capabilities of the Next Generation Diagnostic System (NGDS) Increment (Inc) 2 system and far-forward diagnostic devices, in general. The participants were briefed on the results of this survey, which were used to help determine where and how far-forward diagnostics could make the biggest impact on the DoD's health community.

A.1. Workshop Agenda

The workshop agenda included the following subjects:

- welcome and JUPITR introduction;
- charge to participants and rules of engagement for the day;
- NGDS family of systems overview and Inc 2 introduction;
- review of service medical care roles 1–4;

- draft NGDS Inc 2 Analysis of Alternatives update;
- discussion—the following far-forward CONOPS diagnostics :
 - How far away from military medical centers does it become advantageous for the DoD to provide far-forward military diagnostics?
 - What barriers exist with the use of far-forward diagnostics (i.e., clinical laboratory improvement amendments waiver, cold chain storage, etc.)?
 - At what distance away from an existing medical facility should the military services focus resources for the development of additional systems or infrastructure?
 - Is the benefit worth the cost to introduce handheld diagnostics into the military medical enterprise?
- survey results from the JUPITR ATD far-forward diagnostics survey;
- NGDS Inc 2 disease-specific discussion on the following topics:
 - For pathogens where the DoD has already invested in a Role 3 diagnostic capability (such as Q-Fever, Anthrax, etc.), is there military utility in having a diagnostic capability for some or all of these same diseases at a lower role?
 - What disease specific factors enhance the need for having a diagnostic capability at a lower role (e.g., plague: time to treat = 24 h [pneumonic])?
 - Based on the response to question b on factors of specific diseases, what are the biological warfare agent diseases or emerging infectious diseases that would be operationally relevant in a far-forward medical setting?
- future of NGDS Inc 2 and next steps:
 - What recommendations need to be made to bridge gaps between current CONOPS and the far-forward CONOPS discussed during the workshop?
 - The ability to diagnose radiological and chemical exposure combined with the ability to detect protein toxins suggest that the best case scenario for NGDS Inc 2 would be a protein marker detection tool capable of accomplishing all missions. Current technologies that fit this mission profile are the size of a gym bag. Is this an effective alternative? and
- closing remarks, action items, and path forward.

A.2. Workshop Participants

Table A2 provides an overview of the workshop participants.

Table A2. Participants of the JUPITR ATD Far-Forward CBRN Diagnostics Concepts Workshop

Participant	Organization
Mr. Adam Becker	Joint Project Management (JPM) Medical Countermeasure Systems (MCS), Joint Program Executive Office (JPEO) Chemical and Biological Defense (CBD)
LTC Mark Bohannon	Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND), J8
Dr. Marilyn Bracken	Institute for Defense Analyses, Alexandria, VA
Mr. Robert Brainard	JPM-MCS, JPEO-CBD
Mr. Dave Brune	Office of the Surgeon General (OTSG), Army
Dr. George Christopher	JPM-MCS, JPEO-CBD
LCDR Rollin Clayton	U.S. Marine Corps Forces Command (MARFORCOM)
Mr. Robert Connors	Telemedicine & Advanced Technology Research Center (TATRC), Army
MSG Eric Donovan	Air Force Medical Support Agency (AFMSA)/Air Force Special Operations Command (AFSOC)
Mr. Daniel Dumas	AFMSA/AFSOC
Dr. Peter Emanuel	Joint U.S. Forces Korea Portal and Integrated Threat Recognition (JUPITR) Advanced Technology Demonstration (ATD), JPEO-CBD
COL Mark Goldhagen	Air Force
Mr. Jeff Grotte	IDA
Mr. Lorenzo Hankla	Booz Allen Hamilton, Belcamp, MD
Ms. Megan Holste	Deputy Under Secretary of the Army-Test and Evaluation (DUSA-TE)
CDR Franca Jones	Under Secretary of Defense for Acquisition, Technology, and Logistics (OUSD(AT&L)), Navy

Table A2. Continued

Participant	Organization
MAJ Jay Kost	JRO-CBRND, J8
MAJ Kevin Kupferer	AFMSA
SFC Ed Loudenclos	U.S. Army Medical Department Center and School (AMEDDC&S) Directorate of Combat and Doctrine Development (DCDD)
Dr. Francis McVeigh	TATRC, Army
Mr. James Murray	AMEDDC&S DCDD
Ms. Lorraine Myer	Office of the Chief of Naval Operations (OPNAV)
Dr. Bill Nauschuetz	U.S. Army Medical Command (MEDCOM)
Mr. Sean O'Day	JPM-MCS, JPEO-CBD
Dr. Jason Opdyke	JPM-MCS, JPEO-CBD
CDR Guillermo Pimentel	Naval Medical Research Center (NMRC)
Mr. Rick Prouty	JRO-CBRND, J8
Dr. Chris Renner	JRO-CBRND, J8
LTC Ricardo Reyes	OTSG, Army
LCDR Doug Searles	Bureau of Medicine and Surgery (BUMED), Navy
Dr. Kate Sixt	IDA
MAJ Jonathan Stallings	U.S. Army Center for Environmental Health Research (USACEHR)
Mr. Phi Vu	JPM-MCS, JPEO-CBD
LTC Eric Wagar	U.S. Army Medical Research and Materiel Command (MRMC)
LTC Carol West	AFMSA/SGXH, Air Force
MAJ Sean Chickery	Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Air Force

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Biological Center
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ATTN: Emanuel, P.
Moore, E

Defense Threat Reduction Agency
J9-CBS
ATTN: Graziano, A.

Department of Homeland Security
DHS-ORD-CSAC
ATTN: Famini, G.

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